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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/574,626 05/19/00 REMACLE J VANM159.001A

020995 HM22/0831
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EXAMINER

ZHOU, S

ART UNIT

PAPER NUMBER

1631

10

DATE MAILED:

08/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/574,626

Applicant(s)

REMACLE ET AL.

Examiner

Shubo "Joe" Zhou

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Attachment for PTO-948 (Rev. 03/01 or earlier).

DETAILED ACTION

Applicant's amendment and request for reconsideration in Paper #9, filed on 7/12/01, is acknowledged and the amendments entered unless specifically noted in the following action.

Applicant's arguments in response to the previous Office Action, mailed 2/22/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections from previous Office actions not reiterated herein are hereby withdrawn. The following rejections and/or objections are either reiterated from the previous Office actions, or newly applied, and constitute the complete set presently being applied to the instant application.

It is noticed that claim 27 was not examined in the previous Office action due to an inadvertent error.

Specification

The abstract of the disclosure is objected to because it is not a single paragraph. Correction is required. See MPEP § 608.01(b).

This objection is reiterated and maintained from the previous Office action. Note that applicant's amendment for the Abstract in Paper #9 is not entered because the amended Abstract was not on a separate sheet. A new Abstract on a separate sheet is required.

Applicants are hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled

"Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO-948 was mailed with Paper No. 7 on 2/22/01. Due to the above notification, applicants are required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102(e) that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 6-9, and 28 are rejected under 35 U.S.C. § 102(e) as being anticipated by Van Ness et al. (US patent No. 6,027,890, Issued Feb. 22, 2000, Filed July 22, 1997).

Van Ness et al. disclose a method for detecting biomolecules using array comprising putting into contact target compound with a capture molecule which are fixed upon a surface of solid support according to an array with a density of 10^7 to 10^9 biomolecules per 2000 square microns, which is interpreted being within the scope of "at least 20 discrete regions per cm^2 " as required in the instant claim (columns 73 and 76); performing a reaction leading to formation of a precipitate of 50 micrometer spots, which, as set forth above, is interpreted being within the scope of "a few micrometers from the bound target compound" as required in the instant claim (column 76); and determining the presence of precipitates with such as a CCD-linked microscope

(column 76, lines 31-44). The binding between the target and capture molecule are hybridization between two nucleotide sequences (column 74 and column 76, lines 9-29), as required in the instant claims. The biomolecules can be nucleic acids, proteins/antigens, antibodies, or receptor-ligand pair (column 2). As stated above, the possible presence of the precipitate is detected by a microscope equipped with a CCD camera. It is thus inherent that the image is obtained by reflection of a light beam upon the precipitate, as is well-known in the art that light reflection is one of the working principles in such a microscope equipped with a CCD camera. The methods disclosed by Van Ness et al. make use of the well-known system of biotin-streptavidin/horseradish peroxidase (column 76) and the precipitate is formed using a precipitating substrate. Thus, it is inherent that such a precipitate is formed on the surface of a particle associated with the target compound, as required in the instant claims.

Claim Rejections-35 USC § 103

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abouzied et al. (Journal of AOAC International, Vol. 77, No. 2 (MAR-APR), pp. 495-501, 1994) in view of Howard III et al. (IDS document: EP 0646784A1, 05-04-95) and Van Ness et al. (US patent No. 6,027,890, Issued Feb. 22, 2000, Filed July 22, 1997), and in further view of Roth et al. (US patent # 5,902,727, Issued May 11, 1999, application filing date: Sep. 4, 1996) and Terstappen et al. (US patent # 5,646,001, July 8, 1997).

This rejection is maintained and reiterated for reasons of record as given in the previous Office action, except that the reference of Van Ness et al. is newly applied as necessitated by applicants' amendments.

Applicants argue that none of the cited references teach or suggest methods of detecting a precipitate formed within a few micrometers of the bound target compound on an array comprising a density of at least 20 discrete regions per cm^2 , and thus the cited references do not render the claimed invention obvious. This is not found persuasive because this claim limitation is added in by applicants through amendments. However, the newly added reference, Van Ness et al., teaches of an array with a density of 10^7 to 10^9 biomolecules per 2000 square microns (column 73), which density is within the scope of the instant "at least 20 discrete regions per cm^2 ", and a method of detecting a precipitate formed within 50 micrometers of the bound target compound (column 76), wherein the 50 micrometers is interpreted being within the scope of the instant claim limitation of "a few micrometers".

Claims 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abouzied et al. (Journal of AOAC International, Vol. 77, No. 2 (MAR-APR), pp. 495-501, 1994) in view of Van Ness et al. (US patent No. 6,027,890, Issued Feb. 22, 2000, Filed July 22, 1997), and Gingeras et al. (US patent # 6,228,575, issued May 8, 2001, filed Feb. 7, 1997).

As set forth in the previous Office action, Abouzied et al. disclose a method of simultaneously screening and detection of multianalyte using membrane strips (interpreted as the array of the instant claims) as summarized in the abstract, comprising the steps of contacting analytes (interpreted as the target compounds in the instant claims), with multiple antibodies (interpreted as the capture molecules of the instant claims) to let them bind; precipitation being formed on the membrane upon

binding; detection and quantification of the precipitates by light reflection and video image analysis. The binding as disclosed is a reaction between an antigenic structure and its corresponding antibody as is required in the instant claims and the antibody and its corresponding antigen can be interpreted at a broad sense, as a receptor and its corresponding ligand, as required of the instant claims. The presence of the precipitates is detected by both visual detection of the color intensity by reflection, as required in the instant claims, and for quantification, image is taken by a CCD video camera and is converted into digital form (abstract and Experimental, pages 495-497). Abouzied also disclosed an apparatus, termed "a computer-assisted multianalyte assay system", for the detection and/or quantification of multianalytes, which apparatus comprises detection and/or quantification device including camera, and a computer to collect results including the images taken by the camera, as required in the instant claims (Figure 1 and page 497). A video-digitizing board is equipped with the CCD camera and is interpreted as the sensor as required in the instant claims. The camera is a device for reading information on the array. A computer program for performing the above steps is stored on a computer readable medium, which is in the broad sense the printed paper copy of the publication.

As set forth in the previous sections, Van Ness et al. disclose a method of detecting biomolecules using array and an apparatus for the detection comprising the array on a solid support, a microscope and a CCD camera (column 76). It would have been obvious to one of ordinary skill in the art that such a CCD camera would have been linked to a computer with a program to recognize such images of discrete regions on the array in order to process the images taken by the camera, and to detect/quantitate the target compounds.

Bar code would have been widely used in the art of bioassays. For example, Gingeras et al. disclose a chip-based species identification using array and bar code and an apparatus comprising a computer system and bar code reader (see Figures 14, 15, and 32 and column 7).

In summary, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine the teachings and/or motivations of Abouzied et al., Van Ness et al., and Gingeras et al. to make and use the claimed invention.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

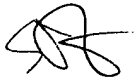
Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is 703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

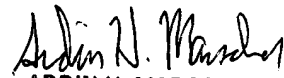
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Art Unit: 1631

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S. "Joe" Zhou, Ph.D.

Patent Examiner



ARDIN H. MARSCHEL
PRIMARY EXAMINER